



Certificate of Mailing: Date of Deposit: April 12, 2007

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Megan Kiley

Printed name of person mailing correspondence

person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Inoue et al.

Art Unit:

Confirmation No.: 7683 1645

Serial No.: 371(c) Date: 10/587.123

January 18, 2007

Examiner:

Not Yet Assigned

Customer No.: 21559

Title:

METHOD FOR PRODUCING VIRAL VECTORS

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449, copies of which are enclosed, with the exception of U.S. patents, U.S. patent application publications, and U.S. patent applications.

Applicants note that AU 200046146 A, CN 1355851 A, EP 1186667 A1, and KR 2002014786 A, are patent family members of WO 00/70070 A1, submitted to the USPTO with the IDS filed on February 14, 2007. Accordingly, copies are not enclosed.

In addition, Applicants list CN 1357044 A on the enclosed Form PTO-1449. CN

1357044 A is cumulative of the WO 00/70055 publication submitted to the USPTO with the IDS filed on February 14, 2007. Accordingly, a copy of CN 1357044 A is not enclosed.

Applicants also note that AU 7335196 A, CA 2236113 A1, CN 1207123 A, B, EP 1325960 A2, and HK 1018287 A1, are patent family members of WO 97/16538 A1 a copy of which is submitted herewith, and copies of the family members are not enclosed.

The enclosed copies of JP 7-509616 A1, JP 10-506542 A1, WO 97/16538 A1, WO 03/092738 A1, WO 03/102183 A1, WO 04/038029, and Hatanaka, M., ed., <u>Uirusugaku</u>, <u>Asakura Shoten</u>, pp. 247-248 (1997), are written in the Japanese language. An English language translation for each of these references is enclosed, with the exception of JP 7-509616 A1, where only an English translation of the claims is enclosed.

Furthermore, WO 97/16171, WO 00/09700 A1, are written in the Japanese language, and WO 00/27430 A2, A3 is written in the German language. In accordance with 37 C.F.R. § 1.98, English language abstracts are provided for these documents.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

This statement is being filed before the receipt of a first Office action on the merits.

If there are any charges or any credits, please apply them to Deposit Account

No. 03-2095.

Respectfully submitted,

Date: 12 April 7007

Clark & Elbing LLP 101 Federal Street Boston, MA 02110 Telephone: 617-428-0200 Facsimile: 617-428-7045





50026/061001 Attorney Docket No. SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (MODIFIED) 10/587,123 Serial No. Applicant Inoue et al. INFORMATION DISCLOSURE 371 (c) Date January 18, 2007 STATEMENT BY APPLICANT (Use several sheets if necessary) 1645 Group (37 C.F.R. § 1.98(b)) IDS Filed April 12, 2007

| U.S. PATENT DOCUMENTS  |                    |                     |                       |       |          |                                 |
|------------------------|--------------------|---------------------|-----------------------|-------|----------|---------------------------------|
| Examiner's<br>Initials | Document<br>Number | Publication<br>Date | Patentee or Applicant | Class | Subclass | Filing Date<br>(If Appropriate) |
|                        | 10/562,408         |                     | You et al.            |       |          | Dec. 23, 2005                   |
|                        | 10/578,085         |                     | Okano et al.          |       |          | May 3, 2006                     |
|                        | 2002/0002143 A1    | Jan. 03, 2002       | Kano et al.           |       |          |                                 |
|                        | 2002/0081706 A1    | Jun. 27, 2002       | Nagai et al.          |       |          |                                 |
|                        | 2002/0098576 A1    | Jul. 25, 2002       | Nagai et al.          |       |          |                                 |
|                        | 2002/0100066 A1    | Jul. 25, 2002       | Nagai et al.          |       |          |                                 |
|                        | 2003/0170210 A1    | Sep. 11, 2003       | Masaki et al.         |       |          |                                 |
|                        | 2003/0170897 A1    | Sep. 11, 2003       | Imai et al.           |       |          |                                 |
|                        | 2003/0203489 A1    | Oct. 30, 2003       | Yonemitsu et al.      |       |          |                                 |
|                        | 2004/0005296 A1    | Jan. 8, 2004        | Yonemitsu et al.      |       |          |                                 |
|                        | 2004/0053877 A1    | Mar. 18, 2004       | Fukumura et al.       |       |          |                                 |
|                        | 2004/0101965 A1    | May 27, 2004        | Griesenbach et al.    |       |          |                                 |
|                        | 2004/0121308 A1    | Jun. 24, 2004       | Nagai et al.          |       |          |                                 |
|                        | 2005/0130123 A1    | Jun. 16, 2005       | Inoue et al.          |       |          |                                 |
|                        | 2005/0221292 A1    | Oct. 6, 2005        | Kinoh et al.          |       |          |                                 |
|                        | 2006/0104950 A1    | May 18, 2006        | Okano et al.          |       |          |                                 |
|                        | 2006/0216824 A1    | Sep. 28, 2006       | Tokusumi et al.       |       |          |                                 |
|                        | 2007/0009949 A1    | Jan. 11, 2007       | Kitazato et al.       |       |          |                                 |
|                        | 5,962,274          | Oct. 5, 1999        | Parks                 |       |          |                                 |
|                        | 6,040,174          | Mar. 21, 2000       | Imler et al.          |       |          |                                 |
|                        | 6,746,860          | Jun. 8, 2004        | Tokusumi et al.       |       |          |                                 |

| EXAMINER /Agrileszka boesen/ |  | DATE CONSIDERED                             |                      |  |
|------------------------------|--|---|----------------------|--|
|                              | al citation considered. Draw line through citation | n if not in conformance and not considered. | Include copy of this |  |

form with the next comment restriction of the state of th

Sheet 2 of 9

50026/061001 Attomey Docket No. SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (MODIFIED) 10/587,123 Serial No. Applicant Inoue et al. INFORMATION DISCLOSURE 371 (c) Date January 18, 2007 STATEMENT BY APPLICANT (Use several sheets if necessary) 1645 Group (37 C.F.R. § 1.98(b)) IDS Filed April 12, 2007

APR 1 6 2007

|   | 6,828,138          | Dec. 7, 2004                | Nagai et al.             |          |                         |                     |
|---|--------------------|-----------------------------|--------------------------|----------|-------------------------|---------------------|
|   | FOREIGN F          | PATENT OR PUBL              | ISHED FOREIGN PATENT APP | LICATION |                         |                     |
| Examiner's Document Publication<br>Initials Number Date |                    | Country or<br>Patent Office | Class                    | Subclass | Translation<br>(Yes/No) |                     |
|   | AU 7335196 A       | May 22, 1997                | Australia                |          |                         |                     |
|   | AU 200046146 A     | Dec. 5, 2000                | Australia /              |          |                         |                     |
|   | CA 2236113 A1      | May 9, 1997                 | Canada                   |          |                         |                     |
|   | CN 1207123 A, B    | Feb. 3, 1999                | China                    |          |                         | No                  |
|   | CN 1357044 A       | Jul. 3, 2002                | China                    |          |                         | No                  |
|   | CN 1355851 A       | Jun. 26, 2002               | China                    |          |                         | No                  |
|   | EP 0863202 A1      | Sep. 9, 1998                | EPO                      |          |                         |                     |
|   | EP 1106692 A1      | Jun. 13, 2001               | EPO                      |          |                         |                     |
|   | EP 1179594 A1      | Feb. 13, 2002               | EPO                      |          |                         |                     |
|   | EP 1186667 A1      | Mar. 13, 2002               | EPO                      |          |                         |                     |
|   | EP 1325960 A2      | Jul. 9, 2003                | EPO                      |          |                         |                     |
|   | HK 1018287 A1      | Nov. 21, 2003               | Hong Kong                |          |                         |                     |
|   | JP 7-509616 A1     | Oct. 26, 1995               | Japan                    | Ī        |                         | Claims only         |
|   | JP 10-506542 A1    | Jun. 30, 1998               | Japan                    |          |                         | Yes                 |
|   | KR 2002014786 A    | Feb. 25, 2002               | Korea                    |          |                         |                     |
|   | WO 97/16171 A1     | May 9, 1997                 | WIPO                     |          |                         | English<br>Abstract |
|   | WO 97/16538 A1     | May 9, 1997                 | WIPO                     |          |                         | Yes                 |
|   | WO 00/09700 A1     | Feb. 24, 2000               | WIPO                     |          |                         | English<br>Abstract |
|   | WO 00/27430 A2, A3 | May 18, 2000                | WIPO                     |          |                         | English<br>Abstract |

| EXAMINER         | /Agnieszka Boe          | sen/                      | DATE CONSIDERED            | 02/19/2008        |                      |
|------------------|-------------------------|---------------------------|----------------------------|-------------------|----------------------|
| EXAMINER: Initia | al citation considered. | Draw line through citatio | n if not in conformance an | d not considered. | Include copy of this |

OIPE 48007

Sheet 3 of 9

| \h_ \d=7/  |  |  |                                    |                            |                              |                       |
|--|--|--|------------------------------------|----------------------------|------------------------------|-----------------------|
| SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE |  |  | Attorney Docket No. 50026/061001   |                            | 001                          |                       |
| (MODIFIED)   | PATENT AND TRA   | DEMARK OFFICE                                | Serial No.                         |                            | 10/587,123                   | 3                     |
|  |  |  | Applicant                          |                            | Inoue et al.                 |                       |
| STATEMENT  | INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT   |  |                                    | е                          | January 18                   | , 2007                |
| (Use several sheets if necessary)  |  |  | Group                              |                            | 1645                         |                       |
| (37 C.F.R. § 1.98(b))  |  |  | IDS Filed                          |                            | April 12, 20                 | 007                   |
|  |  |  |                                    |                            |                              |                       |
| WO 01/32898 A2, A3   | May 10, 2001   | WIPO   |                                    |                            |                              |                       |
| WO 03/092738 A1  | Nov. 13, 2003  | WIPO   |                                    |                            |                              | Yes                   |
| WO 03/102183 A1  | Dec. 11, 2003  | WIPO   |                                    |                            |                              | Yes                   |
| WO 04/038029 A1  | May 6, 2004  | WIPO   |                                    |                            |                              | Yes                   |
| OTHER DOCUM  | NTS (INCLUDING A   | AUTHOR, TITLE, DA                            | TE, PLACE                          | OF PUBLIC                  | ATION)                       |                       |
| Ali and Nayak, "Asser<br>and Transmembrane                                       | nbly of Sendai Virus:<br>Domain of F Protein,  | M Protein Interacts * Virology, 276(2):28    | with F and HI<br>39-303 (2000)     | N Proteins :               | and with the                 | Cytoplasmic Tail      |
| Altenschmidt et al., "S  | Altenschmidt et al., "Specific Cytotoxic T Lymphocytes In Gene Therapy," J. Mol. Med. 75(4):259-266 (1997).  |  |                                    |                            |                              |                       |
| Arai et al., "A New Sy<br>Vector Induction by Ir<br>(1998).                      | Arai et al., "A New System For Stringent, High-Titer Vesicular Stomastis Virus G Protein-Pseudotyped Retrovirus<br>Vedor Induction by Introduction of Cre Recombinase into Stable Prepackaging Cell Lines," J. Virol. 72(2):1115-1121<br>(1998). |  |                                    |                            |                              |                       |
| Auten et al., "Effect of<br>Primary T Cells and M                                | Scaffold Attachment<br>acrophages," Hum.   | t Region on Transge<br>Gene Ther. 10(8):13   | ene Expressio<br>389-1399 (199     | n in Retrov<br>99).        | irus Vector-T                | ransduced             |
| Ayuk et al., "Establish<br>Clinical Requirements                                 | ment of an Optimiser," Gene Ther. 6(10):   | d Gene Transfer Pro<br>1788-1792 (1999).     | tocol for Hurr                     | an Primary                 | T Lymphocy                   | tes According to      |
| Bagai et al., "Hemago<br>Sendai Virus Envelop                                    | lutinin-Neuraminidas<br>es with Cells," J. Viro  | se Enhances F Prote<br>bl. 67(6):3312-3318   | ein-Mediated I<br>(1993).          | Membrane                   | Fusion of Re                 | constituted           |
| Barclay and Palese, *69(2):1275-1279 (199  |  | with Site-Specific Mu                        | itations Introd                    | uced into t                | ne HA Gene,                  | J. Virol.             |
| Bergemann et al., "Ex<br>Recombination," Nuc                                     | cision of Specific DN<br>eic Acids Res. 23(21  | IA-Sequences From<br>):4451-4456 (1995)      | Integrated R                       | etroviral Ve               | ctors Via Site               | e-Specific            |
| Bitzer et al., "Sendai<br>Cleaved F <sub>0</sub> Precursor                       | firus Efficiently Infect<br>Proteins for this Alte   | ts Cells via the Asial<br>mative Route of Ce | loglycoprotein<br>Il Entry," J. Vi | Receptor a<br>rol. 71(7):5 | and Requires<br>481-5486 (19 | the Presence of 197). |
| Blaese et al., "T Lymp<br>270(5235):475-480 (1                                   | hocyte-Directed Gen<br>995).   | ne Therapy for ADA                           | SCID: Initial T                    | rial Result                | s After 4 Year               | rs," Science          |
| Brenner, *Gene Trans   | fer to Hematopoietic   | Cells," N. Eng. J. M                         | led. 335(5):33                     | 7-339 (199                 | 16).                         |                       |
| Brown and Rose, "So<br>to the Apical Cell Sur                                    | ting of GPI-Anchore<br>ace," Cell 68(3):533-   | d Proteins to Glycoli<br>544 (1992).         | pid-Enriched                       | Membrane                   | Subdomains                   | during Transport      |
| Buchschacher and W<br>95(8):2499-2504 (200                                       |  | ment of Lentiviral Ve                        | ctors for Gen                      | e Therapy                  | for Human D                  | iseases," Blood       |

|   | EXAMINER | /Agnieszka Boesen/ | DATE CONSIDERED | 02/19/2008 |  |
|---|----------|--------------------|-----------------|------------|--|
| EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of |          |                    |                 |            |  |



| [ <del>]</del>                                       |                     |                  |
|--|---------------------|------------------|
| SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE | Attorney Docket No. | 50026/061001     |
| (MODIFIED) PATENT AND TRADEMARK OFFICE               | Serial No.          | 10/587,123       |
| ·  | Applicant           | Inoue et al.     |
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT     | 371 (c) Date        | January 18, 2007 |
| (Use several sheets if necessary)                    | Group               | 1645             |
| (37 C.F.R. § 1.98(b))                                | IDS Filed           | April 12, 2007   |

| Bunnell et al., "Efficient In Vivo Marking of Primary CD4+ T Lymphocytes in Nonhuman Primates Using a Gibbon Ape<br>Leukemia Virus-Derived Retroviral Vector," Blood 89(6): 1987-1995 (1997).                          |
|--|
| Caravokyri et al., "Defective Synthesis of Envelope Proteins by Temperature-Sensitive Mutants Representing Complementation Groups B and D of Respiratory Syncytial Virus," J. Gen. Virol. 72(Pt. 10):2501-2508 (1991). |
| Cathomen et al., "A Matrix-Less Measles Virus Is Infectious and Elicits Extensive Cell Fusion: Consequences for<br>Propagation in the Brain," <i>EMBO J.</i> 17(14):3899-3908 (1998).                                  |
| Cathomen et al., "Measles Viruses with Altered Envelope Protein Cytoplasmic Tails Gain Cell Fusion Competence,"<br>J. Virol. 72(2):1224-1234 (1998).   |
| Chen et al., "A Unique Substrate Recognition Profile for Matrix Metalloproteinase-2," J. Biol. Chem. 277(6):4485-4491 (2002).  |
| Conzelmann, "Nonsegmented Negative-Strand RNA Viruses: Genetics and Manipulation of Viral Genomes," Annu. Rev. Genet., 32:123-162 (1998).  |
| Costello et al., "Gene Transfer into Stimulated and Unstimulated T Lymphocytes by HIV-1-Derived Lentiviral Vectors,"<br>Gene Ther. 7(7):596-604 (2000).  |
| Dardalhon et al., "Lenlivirus-mediated Gene Transfer in Primary T Cells Is Enhanced by a Central DNA Flap," Gene Ther. 8(3):190-198 (2001).  |
| Di Nicola et al., "Recombinant Adenoviral Vector-LipofectAMINE Complex for Gene Transduction into Human T Lymphocytes," Hum. Gene Ther. 10(11):1875-1884 (1999).   |
| Douglas et al., "Targeted Gene Delivery by Tropism-Modified Adenoviral Vectors," Nature Biotechnol. 14(11):1574-1578 (1996).   |
| Friedman, "Expression of Human Adenosine Dearminase Using a Transmissable Murine Retrovirus Vector System,"<br>Proc. Natl. Acad. Sci. USA 82(3):703-707 (1985).  |
| Garoff et al., "Virus Maturation by Budding," Microbiol. Mol. Biol. Rev. 62(4):1171-1190 (1998).   |
| Ghivizzani et al., 'Direct Retrovirus-Mediated Gene Transfer to the Synovium of the Rabbit Knee: Implications for Arthritis Gene Therapy," Gene Ther. 4(9):977-982 (1997).   |
| Gitman et al., "Use of Virus-Attached Antibodies or Insulin Molecules to Mediate Fusion Between Sendai Virus<br>Envelopes and Neuraminidase-Treated Cells," <i>Biochemistry</i> 24(11):2762-2768 (1985).               |
| Gladow et al., "MLV-10A1 Retrovirus Pseudotype Efficiently Transduces Primary Human CD4* T Lymphocytes," J. Gene Med. 2(6):409-415 (2000).   |
| Gómez-Puertas et al., "Influenza Virus Matrix Protein Is the Major Driving Force in Virus Budding," J. Virol. 74(24):11538-11547 (2000).   |

| EXAMINER /Agnieszka Boesen/ | DATE CONSIDERED | 02/19/2008 |
|-----------------------------|-----------------|------------|
|-----------------------------|-----------------|------------|



Sheet 5 of 9

| \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\ |                                 |                     |                  |
|--|---------------------------------|---------------------|------------------|
| SUBSTITUTE FORM PTO-1449               | U.S. DEPARTMENT OF COMMERCE     | Attorney Docket No. | 50026/061001     |
| (MODIFIED)                             | PATENT AND TRADEMARK OFFICE     | Serial No.          | 10/587,123       |
|  |                                 | Applicant           | Inoue et al.     |
| STATEMEN                               | ON DISCLOSURE<br>T BY APPLICANT | 371 (c) Date        | January 18, 2007 |
| (Use several sheets if necessary)      |                                 | Group               | 1645             |
| (37 C.F.R. § 1.98(b))                  |                                 | IDS Filed           | April 12, 2007   |

| Gould, "Comparison of the Deduced Matrix and Fusion Protein Sequences of Equine Morbillivirus with Cognate Genes of the Paramyxoviridae," Virus Res. 43(1):17-31 (1996).  |
|---|
| Harcourt et al., "Molecular Characterization of Nipah Virus, a Newly Emergent Paramyxovirus," Virology 271(2):334-349 (2000).   |
| Hasan et al., "Creation of an Infectious Recombinant Sendal Virus Expressing the Firefly Luciferase Gene from the 3' Proximal First Locus," J. Gen. Virol. 78(Pt 11):2813-2820 (1997).  |
| Hatanaka, M., ed., <u>Uirusugaku, Asakura Shoten</u> , pp. 247-248 (1997) (with English language translation).  |
| Hege and Roberts, "T-Cell Gene Therapy," Curr. Opin. Biotechnol. 7(6):629-634 (1996).   |
| Heggeness et al., "In Vitro Assembly of the Nonglycosylated Membrane Protein (M) of Sendai Virus," Proc. Natl. Acad. Sci. USA 79(20):6232-6236 (1982).  |
| Huntley et al., "Phosphorylation of Sendal Virus Phosphoprotein by Cellular Protein Kinase C \( \xi_s \) . Biol. Chem. 272(26):16578-16584 (1997).  |
| Ikeda et al., "Recombinant Sendai Virus-Mediated Gene Transfer into Adult Rat Retinal Tissue: Efficient Gene Transfer by Brief Exposure," Exp. Eye Res. 75(1):39-48 (2002).   |
| Imbert et al., "Highly Efficient Retroviral Gene Transfer into Human Primary T Lymphocytes Derived from Peripheral Blood," Cancer Gene Ther. 1(4):259-265 (1994).   |
| <br>Johnson et al., "Metalloproteinase Cleavable Linkers Can Target the Cytotoxicity of Fusogenic Membrane<br>Glycoproteins in Gliomas," Abstracts from the Fourth Annual Meeting of the American Society of Gene Therapy; Mol.<br>The. 3(5):25(3)(2001).                                   |
| Karron et al., "Respiratory Syncytial Virus (RSV) SH and G Proteins Are Not Essential for Viral Replication In Vitro:<br>Clinical Evaluation and Molecular Characterization of a Cold-Passaged, Attenuated RSV Subgroup B Mutant," Proc.<br>Natl. Acad. Sci. USA 94(25): 1396-13966 (1991). |
| Kato et al., "Initiation of Sendai Virus Multiplication from Transfected cDNA or RNA with Negative or Positive Sense,"<br>Genes Cells 1(6):569-579 (1996).  |
| Kido et al., "The Human Mucus Protease Inhibitor and its Mutants Are Novel Defensive Compounds against Infection with Influenza A and Sendai Viruses," <i>Biopolymers</i> 51(1):79-86 (1999).   |
| Kondo et al., "Temperature-Sensitive Phenotype of a Mutant Sendai Virus Strain is Caused by its Insufficient Accumulation of the M Protein," <i>J. Biol. Chem.</i> 268(29):21924-21930 (1993).  |
| Kridel et al., "Substrate Hydrolysis by Matrix Metalloproteinase-9," J. Biol. Chem. 276(23):20572-20578 (2001).   |
| Kühlcke et al., "Highly Efficient Retroviral Gene Transfer Based on Centrifugation-Mediated Vector Preloading of Tissue Culture Vessels," Mol. Ther. 5(4):473-478 (2002).   |
|   |

| EXAMINER         | /Agnieszka Boese           | en/                       | DATE CONSIDERED         | 02/19/2008         |                      |
|------------------|----------------------------|---------------------------|-------------------------|--------------------|----------------------|
| EXAMINER: Initia | al citation considered. Dr | raw line through citation | if not in conformance a | nd not considered. | Include copy of this |



Sheet 6 of 9

|  | SUBSTITUTE FORM PTO-1449  | U.S. DEPARTMENT OF COMMERCE | Attorney Docket No. | 50026/061001     |
|--|---|-----------------------------|---------------------|------------------|
|  | (MODIFIED)  | PATENT AND TRADEMARK OFFICE | Serial No.          | 10/587,123       |
|  | INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br>(Use several sheets if necessary) |                             | Applicant           | Inoue et al.     |
|  |   |                             | 371 (c) Date        | January 18, 2007 |
|  |   |                             | Group               | 1645             |
|  | (37 C.F.R. § 1.98(b))   |                             | IDS Filed           | April 12, 2007   |

| Leyrer et al., "Sendai Virus-Like Particles Devoid of Haemagglutinin-Neuraminidase Protein Infect Cells Via the Human Asialoglycoprotein Receptor," J. Gen. Virol. 79(Pt. 4):883-687 (1998).                                     |
|--|
| Li et al., "Effect of Cleavage Mutants on Syncytium Formation Directed by the Wild-Type Fusion Protein of Newcastle Disease Virus," <i>J. Virol.</i> 72(5):3789-3795 (1998).   |
| Lin et al., "The RNA Binding Region of the Paramyxovirus SV5 V and P Proteins," Virology 238(2):460-469 (1997).  |
| Manié et al., "Measles Virus Structural Components Are Enriched into Lipid Raft Microdomains: A Potential Cellular Location for Virus Assembly," J. Virol. 74(1):305-311 (2000).   |
| Markwell et al., "An Alternative Route of Infection for Viruses: Entry by Means of the Asialoglycoprotein Receptor of a<br>Sendal Virus Mutant Lacking its Attachment Protein," Proc. Natl. Acad. Sci. USA 82(4):978-982 (1985). |
| Martin et al., "Retrovirus Targeting by Tropism Restriction to Melanoma Cells," J. Virol. 73(8):6923-6929 (1999).  |
| Matsumura et al., "RNA Editing-Like Phenomenon in Paramyxovirus V Gene mRNA Observed in Insect Cells Infected With a Recombinant Baculovirus," J. Gen. Virol. 80(Pt. 1):117-123 (1999).  |
| Mebatsion et al., "Budding of Rabies Virus Particles in the Absence of the Spike Glycoprotein," Cell 84(6):941-951 (1996).   |
| Mebatsion et al., "Matrix Protein of Rabies Virus Is Responsible for the Assembly and Budding of Bullet-Shaped Particles and Interacts with the Transmembrane Spike Glycoprotein G," J. Virol. 73(1):242-250 (1999).             |
| Misaki et al., "Gene-Transferred Oligodonal T Cells Predominantly Persist in Peripheral Blood From an Adenosine Deaminase-Deficient Patient During Gene Therapy," Mol. Ther. 3(1):24-27 (2001).                                  |
| Miura et al., "HVJ (Sendai Virus)-Induced Envelope Fusion and Cell Fusion Are Blocked by Monocional Anti-HN Protein Antibody That Does Not Inhibit Hemagglutination Activity of HVJ," Exp. Cell Res. 141(2):409-420 (1982).      |
| Morikawa et al., "Characterization of Temperature-Sensitive Mutants of Measles Virus," Kilasafo Arch. Exp. Med. 64(1):15-30 (1991).  |
| Mottet et al., "Characterization of Sendai Virus M Protein Mutants that Can Partially Interfere with Virus Particle Production," J. Gen. Virol. 80(Pt. 11):2977-2986 (1999).   |
| Mottet et al., "A Sendai Virus Vector Leading to the Efficient Expression of Mutant M Proteins Interfering with Virus Particle Budding," Virology 221(1):159-171 (1996).   |
| Movassagh et al., "Retrovirus-Mediated Gene Transfer into T Cells: 95% Transduction Efficiency Without Further In Vitro Selection," Hum. Gene Ther. 11(8):1189-1200 (2000).  |
| Nagai, "Paramyxovirus Replication and Pathogenesis. Reverse Genetics Transforms Understanding," Rev. Med. Virol. 9(2):83-99 (1999).  |
| Nieuwenhuizen et al., "Fluorogenic Peptide Amide Substrates for the Estimation of Plasminogen Activators and Plasmin," Anal. Biochem. 83(1):143-148 (1977).  |
|  |

| EXAMINER /Agnieszka Boesen/                                       | DATE CONSIDERED 02/19/2008                                       |     |
|---|--|-----|
| EXAMINER: Initial citation considered. Draw line through citation | n if not in conformance and not considered. Include copy of this |     |
| form white never enterior ces consider                            | ED EXCEPT WHERE LINED THROUGH. /                                 | AB/ |



| (A)  |                     |                  |
|--|---------------------|------------------|
| SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE | Attorney Docket No. | 50026/061001     |
| (MODIFIED) PATENT AND TRADEMARK OFFICE               | Serial No.          | 10/587,123       |
|  | Applicant           | Inoue et al.     |
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT     | 371 (c) Date        | January 18, 2007 |
| (Use several sheets if necessary)                    | Group               | 1645             |
| (37 C.F.R. § 1.98(b))                                | IDS Filed           | April 12, 2007   |

| Okano et al., "Recombinant Sendai Virus Vectors for Activated T Lymphocytes," Gene Ther. 10(16):1381-1391 (2003).   |
|---|
| Peng et al., "Selective Transduction of Protease-Rich Tumors by Matrix-Metalloproteinase-Targeted Retroviral Vectors," Gene Ther. 6(9):1552-1557 (1999).  |
| Poliok et al., "High-Efficiency Gene Transfer into Normal and Adenosine Dearninase-Deficient T Lymphocytes is<br>Mediated by Transduction on Recombinant Fibronectin Fragments," J. Virol. 72(6):4882-4892 (1998).        |
| Ponimaskin et al., "Sendai Virosomes Revisited: Reconstitution with Exogenous Lipids Leads to Potent Vehicles for<br>Gene Transfer," Virology 269(2):391-403 (2000).  |
| Puls and Minchin, "Gene Transfer and Expression of a Non-Viral Polycation-Based Vector in CD4 <sup>+</sup> Cells," <i>Gene Ther.</i> 6(10):1774-1778 (1999).  |
| Ramani et al., "Novel Gene Delivery to Liver Cells Using Engineered Virosomes," FEBS Lett. 404(2-3):164-168 (1997).   |
| Rosenberg et al., 'Gene Transfer Into Humans-Immunotherapy of Patients with Advanced Melanoma, Using Tumor-<br>Infiltrating Lymphocytes Modified by Retroviral Gene Transduction," N. Eng. J. Med. 323(9):570-578 (1990). |
| Rudoll et al., "High-Efficiency Retroviral Vector Mediated Gene Transfer into Human Peripheral Blood CD4* T Lymphocytes," <i>Gene Ther.</i> 3(8):695-705 (1996).  |
| Sakai et al., "Accommodation of Foreign Genes into the Sendai Virus Genome: Sizes of Inserted Genes and Viral Replication," FEBS Lett. 456(2):221-226 (1999).   |
| Sanderson et al., "Sendai Virus Assembly: M Protein Binds to Viral Glycoproteins in Transit through the Secretory Pathway," J. Virol. 67(2):651-663 (1993).   |
| Sanderson et al., "Sendai Virus M Protein Binds Independently to either the F or the HN Glycoprotein In Vivo," J. Virol. 68(1):69-76 (1994).  |
| Schwartz et al., "Synthetic DNA-Compacting Peptides Derived from Human Sequence Enhance Cationic Lipid-Mediated Gene Transfer In Vitro and In Vivo," Gene Ther. 6(2):282-292 (1999).                                      |
| Shiotani et al. "Skeletal Muscle Regeneration After Insulin-Like Growth Factor I Gene Transfer by Recombinant Sendai Virus Vector," Gene Ther. 8(14):1043-1050 (2001).  |
| Simons and Ikonen, "Functional Rafts in Cell Membranes," Nature 387(6633):569-572 (1997).   |
| Spiegel et al., "Pseudotype Formation of Moloney Murine Leukemia Virus with Sendai Virus Glycoprotein F," J. Virol. 72(6):5296-5302 (1998).   |
| Spielhofer et al., "Chimeric Measles Viruses with a Foreign Envelope," J. Virol. 72(3):2150-2159 (1998).  |
|   |

| E  | XAMINER | /Agnieszka Boe             | sen/                      | DATE CONSIDERED                      | 02/19/2008 |
|--|---------|----------------------------|---------------------------|--------------------------------------|------------|
| EXAMINER: Initial citation considered. Draw line through |         | Draw line through citation | if not in conformance and | not considered. Include copy of this |            |



Sheet <u>8</u> of <u>9</u>

| SUBSTITUTE FORM PTO-1449          | U.S. DEPARTMENT OF COMMERCE                      | Attorney Docket No. | 50026/061001     |
|-----------------------------------|--|---------------------|------------------|
| (MODIFIED)                        | PATENT AND TRADEMARK OFFICE                      | Serial No.          | 10/587,123       |
|                                   |  | Applicant           | Inoue et al.     |
| STATEMEN                          | INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT | 371 (c) Date        | January 18, 2007 |
| (Use several sheets if necessary) | Group  | 1645                |                  |
| (37 C.F.R. § 1.98(b))             |  | IDS Filed           | April 12, 2007   |

| Stockschläder et al., "Expansion and Fibronectin-Enhanced Retroviral Transduction of Primary Human T Lymphocytes for Adoptive Immunotherapy," <i>J. Hemalother. Stem Cell Res.</i> 8(4):401-410 (1999).                   |
|---|
| Stone-Hulslander and Morrison, "Detection of an Interaction Between the HN and F Proteins in Newcastle Disease<br>Virus-Infected Cells," J. Virol. 71(9):6287-6295 (1997).  |
| Stricker et al., "The Sendai Virus Matrix Protein Appears to be Recruited in the Cytoplasm by the Viral Nucleocapsid to Function in Viral Assembly and Budding," J. Gen. Virol. 75(Pt. 5):1031-1042 (1994).               |
| Stricker and Roux, "The Major Glycoprotein of Sendai Virus Is Dispensable for Efficient Virus Particle Budding," J. Gen. Virol. 72(Pt. 7):1703-1707 (1991).   |
| Taira et al., "Transfection of Sendai Virus F Gene cDNA with Mutations at its Cleavage Site and HN Gene cDNA into COS Cells Induces Cell Fusion," Arch. Virol. 140(1):187-194 (1995).                                     |
| Takimoto et al., "Role of Matrix and Fusion Proteins in Budding of Sendai Virus," J. Virol. 75(23):11384-11391 (2001).  |
| Tanabayashi et al., "Effect on Fusion Induction of Point Mutations Introduced into the F Protein of Mumps Virus,"<br>Virology 204(2):851-853 (1994).  |
| Tashiro et al., "Changes in Specific Cleavability of the Sendai Virus Fusion Protein: Implications for Pathogenicity In Mice," J. Gen. Virol. 73(Pt. 6):1575-1579 (1992).   |
| Thompson and Portner, "Localization of Functional Sites on the Hemagglutinin-Neuraminidase Glycoprotein of Sendai Virus by Sequence Analysis of Antigenic and Temperature-Sensitive Mutants," Virology 160(1):1-8 (1987). |
| <br>Tomasi et al., "Conjugation of Specific Antibodies to Sendai Virus Particles," FEBS Lett. 143(2):252-256 (1982).  |
| Tuffereau et al., "The Role of Haemagglutinin-Neuraminidase Glycoprotein Cell Surface Expression in the Survival of Sendai Virus-Infected BHK-21 Cells," <i>J. Gen. Virol.</i> 66(Pt. 11):2313-2318 (1985).               |
| <br>Tuohy and Mathisen, "T Cell Design for Therapy in Autoimmune Demyelinating Disease," J. Neuroimmunol. 107(2): 226-232 (2000).   |
| Turk et al., "Determination of Protease Cleavage Site Motifs Using Mixture-Based Oriented Peptide Libraries," Nature Biotechnol. 19(7):661-667 (2001).  |
| Uchida et al., "High Efficiency Gene Transfer into Murine T Cell Clones Using a Retroviral Vector," J. Immunol. 136(5):1876-1879 (1986).  |
| Wickham et al., "Targeted Adenovirus-Mediated Gene Delivery to T Cells Via CD3," J. Virol. 71(10):7663-7669 (1997).   |
| Yao et al., "Differences in the Role of the Cytoplasmic Domain of Human Parainfluenza Virus Fusion Proteins," J. Virol. 69(11):7045-7053 (1995).  |

|   | EXAMINER | /Agnieszka Boesen/ | DATE CONSIDERED | 02/19/2008 |  |
|---|----------|--------------------|-----------------|------------|--|
| EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next contractive production of the contractive production of the contractive productive |          |                    |                 | /AR/       |  |

O 1 P E 4007 St.

Sheet 9 of 9

| SUBSTITUTE FORM PTO 1949 REPORT DEPARTMENT OF COMMERCE | Attorney Docket No. | 50026/061001     |
|--|---------------------|------------------|
| (MODIFIED) PATENT AND TRADEMARK OFFICE                 | Serial No.          | 10/587,123       |
|  | Applicant           | Inoue et al.     |
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT       | 371 (c) Date        | January 18, 2007 |
| (Use several sheets if necessary)                      | Group               | 1645             |
| (37 C.F.R. § 1.98(b))                                  | IDS Filed           | April 12, 2007   |

| Yonemitsu et al., "Efficient Gene Transfer to Airway Epithellum Using Recombinant Sendai Virus," <i>Nature Biotechnol.</i> 18(9):970-973 (2000).                |
|---|
| Yoshida et al., "Membrane (M) Protein of HVJ (Sendai Virus): Its Role in Virus Assembly," Virology 71(1):143-161 (1976).  |
| Yoshida et al., "Studies on the Role of M Protein in Virus Assembly Using a ts Mutant of HVJ (Sendai Virus)," Virology 92(1):139-154 (1979).                    |
| Yu et al., "Sendai Virus-Based Expression of HIV-1 gp120: Reinforcement by the V(-) Version," Genes to Cells 2(7):457-466 (1997).                               |
| Zhirnov et al., "Solubilization of Matrix Protein M 1/M from Virions Occurs at Different pH for Orthomyxo-and Paramyxoviruses," Virology 176(1):274-279 (1990). |

|   | EXAMINER | /Agnieszka Boesen/ | DATE CONSIDERED | 02/19/2008 |
|---|----------|--------------------|-----------------|------------|
| ш |          |                    |                 |            |